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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/625,424	07/23/2003	Tiecheng A. Qiao	85504D-W	9183

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EXAMINER	
HYUN, PAUL SANG HWA	
ART UNIT	PAPER NUMBER
1743	

DATE MAILED: 09/18/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/625,424

Applicant(s)

QIAO ET AL.

Examiner

Paul S. Hyun

Art Unit

1743

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 01 September 2006.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-19 is/are pending in the application.
- 4a) Of the above claim(s) 18 and 19 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-17 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date _____

- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date _____
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: _____

DETAILED ACTION

REMARKS

Request for continued examination submitted by Applicants has been acknowledged. Claims 1-19 are pending, but claims 18 and 19 have been withdrawn from consideration. Claim 1 has been amended. Claim 1 now recites a colorless colorant. The amendment has changed the scope of claims 1-17.

The claim objections cited in the previous Office action is withdrawn in light of the amendments.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Claims **1-5, 7-12, 14-17** are rejected under 35 U.S.C. 103(a) as being unpatentable over Chee et al. (US 6,429,027 B1) in view of Leblans et al. (US 2004/0069857 A1).

Chee et al. disclose a two-dimensional array of microspheres randomly immobilized in wells of a substrate (see Figs. 1A, 1B and line 2, col. 5), wherein the concentration of the microspheres can range from a single microsphere to 2 billion microspheres per cm^2 (see lines 1-33, col. 6). The size of the microspheres can range between 0.2 to 200 microns (see lines 33-40, col. 9). The microspheres bear biological probes in the form of a bioactive agent (i.e. nucleic acids [see claim 12]) that binds an analyte of interest (see claim 1). The microspheres can comprise a dye in the form of chromophores that can be developed to produce a unique optical signature that allows one to visually identify the microspheres and the bioactive agent bound to the microspheres (see claim 5 and line 25, col. 21). Chromophores as defined by the Specification absorb light and convert the absorbed light into heat, which is a photo initiated process (see lines 8-10, col. 2).

The microspheres disclosed by Chee et al. differ from the claimed invention in that the reference does not disclose that the dye is a colorless dye that can be developed to a colored state.

Leblans et al. disclose photochromic dyes for identifying microspheres (see [0056]). The disclosed photochromic dyes are colorless and undergo an irreversible change in light absorption in the presence of specific wavelengths of electromagnetic radiation. The reference discloses that the photochromic dyes are advantageous because the color change is irreversible.

It would have been obvious to one of ordinary skill in the art to use the photochromic dyes disclosed by Leblans et al. to identify the microspheres disclosed by

Chee et al. since the photochromic dyes disclosed by Leblans et al. undergo permanent color change.

Claim 13 is rejected under 35 U.S.C. 103(a) as being unpatentable over Chee et al. in view of Leblans et al. as applied to claims 1-5, 7-12, 14-17, and further in view of Wang (US 4,663,277).

Neither Chee et al. nor Leblans et al. disclose the immobilization of the microspheres by a gelation process.

Wang discloses an immunoassay for a virus accomplished by utilizing microspheres coated with antiviral antibodies. The reference discloses that the method of the immunoassay involves immobilizing the microspheres by placing the microspheres in a gel (see lines 46-50 col. 9).

It would have been obvious to one of ordinary skill in the art to further immobilize the modified microspheres disclosed by Chee et al. and Leblans et al. by means of a gel as taught by Wang so that the microspheres are better secured within the wells of the substrate.

Claims 1, 3, 5 and 6 are rejected under 35 U.S.C. 103(a) as being unpatentable over Chee et al. in view of Litt (US 4,092,408).

Chee et al. disclose a two-dimensional array of microspheres randomly immobilized in wells of a substrate (see Figs. 1A, 1B and line 2, col. 5), wherein the concentration of the microspheres can range from a single microsphere to 2 billion

microspheres per cm^2 (see lines 1-33, col. 6). The size of the microspheres can range between 0.2 to 200 microns (see lines 33-40, col. 9). The microspheres bear biological probes in the form of a bioactive agent (i.e. nucleic acids [see claim 12]) that binds an analyte of interest (see claim 1). The microspheres can comprise a dye in the form of chromophores that can be developed to produce a unique optical signature that allows one to visually identify the microspheres and the bioactive agent bound to the microspheres (see claim 5 and line 25, col. 21).

The microspheres disclosed by Chee et al. differ from the claimed invention in that the reference does not disclose that the dye is a colorless dye that can be developed to a colored state.

Litt discloses an enzyme label that interacts with colorless o-nitrophenol dyed sugar to produce a measurable color intensity (see lines 45-55, col. 7). The enzyme cleaves the sugar from the dye and releases the dye. The intensity of the color is proportional to the enzyme activity.

It would have been obvious to one of ordinary skill in the art to provide the microspheres disclosed by Chee et al. with the dye label disclosed by Litt since the label disclosed by Litt allows the quantification of enzyme activity directly from the intensity of the color produced by the enzyme reaction.

Response to Arguments


Applicant's arguments with respect to claims 1-17 have been considered but are moot in view of the new grounds of rejection. The amendments made to the claims changed the scope of the claims and necessitated new grounds of rejection.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Paul S. Hyun whose telephone number is (571)-272-8559. The examiner can normally be reached on Monday-Friday 8AM-4:30PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jill Warden can be reached on (571)-272-1267. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

PSH
9/12/06


Jill Warden
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